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IN THE

Supreme Court of the United States

KSR International Co.,

Petitioner,

v.

Teleflex, Inc. et al.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF THE UNITED INVENTORS ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF THE RESPONDENTS

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Interest of the *Amicus Curiae*[1]

This brief is filed on behalf of the United Inventors Association ("UIA"), in support of Respondents Teleflex Inc. and Technology Holding Company ("Teleflex"). The UIA is a non-profit educational institution, as defined by the Code of the Internal Revenue Service, 26 U.S.C. § 501(c)(3). As the world's leading inventor organization, the UIA reaches more than 10,000 individual inventors and entrepreneurs, small business enterprise and service providers, and a massive network of regional organizations unified with a single goal: inventor and entrepreneur education. The UIA is thus well positioned to demonstrate the flaws in the Petitioner's approach and to explain why the Federal Circuit's approach is necessary to the proper functioning of the patent system.

The UIA urges this Court to apply the obviousness test developed by the Federal Circuit to prevent the statutorily proscribed, dangerous effects of hindsight in evaluating patent validity. It would be difficult, if not impossible, to name a single corporation that could not be traced back to only a single inventor or entrepreneur, or perhaps a handful of inspired innovators gathered in a garage or basement. Apart from perseverance, the best hope for typical inventors and entrepreneurs is sound and reliable patent protection.

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[1] This brief of amicus curiae is presented by the United Inventors Association pursuant to Rule 37.3(b) of the Rules of the Supreme Court of the United States. Pursuant to Rule 37.6 of the Rules of the Supreme Court of the United States, the UIA states that no counsel for a party authored this brief, in whole or in part, and that no person or entity other than UIA has made a monetary contribution to the preparation or submission of this brief. Counsel for the UIA prepared this brief on a *pro bono* basis. This brief is filed with the consent of both parties, and their consent letters are on file with the Clerk's Office.

The UIA's primary concern is that the position of Petitioner could result in existing patents readily being challenged by adversaries armed with hindsight. Existing patents that have been hard earned could well be subject to *post-facto* judgment on a basis that ignores the very qualities of vision and thoughtful inquiry which are always at the heart of any genuine innovation. While large business may be only slightly impacted; small business concerns and struggling innovators are certain to face an instant and devastating diminishment of corporate value. It is this grave danger to this country's inventor and entrepreneur community that the UIA wishes to address.

Introduction

The implications of this case reach far beyond the parties currently before the Court. This case, indeed any intellectual property case before the Court, implicates the United States' status in this increasingly globalized world. In today's "flat world" economy, as coined by Thomas Friedman in his book, the only area in which the United States is competitive is in technology, knowledge, and intellectual property. In a "flat world," there is a great incentive to develop a new product or process because it can achieve world-wide scale virtually instantly. THOMAS L. FRIEDMAN, THE WORLD IS FLAT: A BRIEF HISTORY OF THE TWENTY-FIRST CENTURY 246 (Farrar, Straus & Giroux 2005).

It is common knowledge that no country respects and protects intellectual property better than the United States; as a result, the United States attracts inventors and innovators from around the world to come here to work and lodge their intellectual property. The quality of American intellectual property protection enhances and encourages people and firms to develop technological innovations. The new ideas that emerge from research and development enable affluent nations like the United State to successfully compete in the global marketplace. NATIONAL SCIENCE FOUNDATION, SCIENCE AND ENGINEERING INDICATORS 2006 6-8 (Feb. 2006). Shapiro and Hassett's economic research concluded that economically-powerful forms of intellectual property, embodied in innovations, are the largest single factor driving economic growth and development, and that intellectual property protections are critical for the development and diffusion of those innovations. ROBERT J. SHAPIRO & KEVIN A. HASSETT, THE ECONOMIC VALUE OF INTELLECTUAL PROPERTY 27 (Oct. 2005).

The importance of intellectual property protection to the American economy simply cannot be overstated. U.S. intellectual property today is worth between $5 trillion and $5.5 trillion; equivalent to about forty-five percent of U.S. Gross Domestic Product ("GDP") and greater than the GDP of any other nation in the world. *Id.* at 18. United States intellectual property industries ("IP Industries") contribute "nearly 40% of the growth achieved by all U.S. private industry and nearly 60% of the growth of U.S. exportable products and services." STEPHEN E. SIWEK, ENGINES OF GROWTH: ECONOMIC CONTRIBUTIONS OF THE US INTELLECTUAL PROPERTY INDUSTRIES, ECONOMISTS INC. (2005) (commissioned by NBC Universal). In addition, "GDP 10-year growth estimates would be approximately 30% lower than current predictions without the contributions of these [IP] industries." *Id.* US IP industries employ eighteen million workers who earn on average forty percent more than all American workers. *Id.*

The United States has traditionally maintained a large surplus when trading intellectual property, and it continues to be a net exporter of manufacturing technological know-how sold as intellectual property. Royalties and fees from foreign firms were, on average, three times greater than those paid out to foreigners by United States firms for access to their technology. In 2003, United States receipts from the licensing of technological know-how to foreigners totaled $4.9 billion, 24.4% higher than in 1999. The most recent data show a trade surplus of $2.6 billion in 2003, 28% higher than the prior year but still lower than the $3.0 billion surplus recorded in 2000. In 2003, US trade in intellectual property produced a surplus of $28.2 billion, up about 5% from the $25.0 billion surplus recorded in 2002, and about 75% of transactions involved exchanges of intellectual property between United States firms and their foreign affiliates. NATIONAL SCIENCE FOUNDATION, *supra*, at 6-23.

These trends suggest both a growing internationalization of US business and a growing reliance on intellectual property developed overseas. In order to maintain this surplus, and to continue to promote the export of American technology, it is essential that American innovations receive strong intellectual property protection.

The USPTO itself supports efforts and initiatives to strengthening intellectual property protection and curb theft of intellectual property. One of its stated strategies is to "[i]ncrease our presence and activities domestically and internationally to advocate U.S. Government IP policy so that U.S. businesses and innovators can better secure and enforce their IP rights." UNITED STATES PATENT & TRADEMARK OFFICE, DRAFT STRATEGIC PLAN 2007-2012, *available at* http://www.uspto.gov/web/offices/com/strat2007.

The major barrier to increasing exportation of American innovation through licensing is the theft of American intellectual property. Shapiro and Hassett rightly recognize the grave danger posed by rampant piracy of intellectual property worldwide, including counterfeiting and other violations of intellectual property rights. The Organization for Economic Development conservatively estimates that the total costs of counterfeiting are equivalent to 5 percent to 7 percent of world trade. The United States, as the world's largest economy with the greatest levels of patenting and copyright activity, is especially harmed by counterfeiting: based on United States good exports of more than $807 billion in 2004, and the OECD's 7 percent estimate of direct costs, counterfeiting alone cost the American economy more than $56 billion in 2004. SHAPIRO & HASSETT, *supra*, at 19-20.

The Federal Bureau of Investigation reports that US companies lose $200 billion to $250 billion annually due to worldwide copyright, trademark, and trade secret infringement. The European Commission concludes that five to seven percent of world trade is composed of counterfeit goods, and reports that the value of counterfeiting as a percentage of world trade is growing: between 1990 and 1999 it doubled from 3.5 percent to seven percent. This growth rate reflects the rapid globalization of the world's economy and a corresponding lack of anti-counterfeiting protections. PAT CHOATE, HOT PROPERTY: THE STEALING OF IDEAS IN AN AGE OF GLOBALIZATION 12 (Alfred A. Knopf 2005).

Accordingly, any review of the United States' patent laws must occur against the backdrop of the increasing importance of the United States' intellectual property laws to American businesses. Strong intellectual property protection is essential for American firms to continue to thrive in today's "flat world."

Summary of the Argument

If Petitioner had moved for summary judgment that Teleflex's pedal assembly was defectively designed and unreasonably dangerous and if Petitioner had supported its motion with two conclusory expert affidavits and if the district court had granted summary judgment without a hearing and without, even, oral argument, then an appellate court would not hesitate to reverse the district court and remand the case for further proceedings.

Here, however, Teleflex has sustained a greater defeat. Its product has not been found defectively designed and unreasonably dangerous, but rather, its intellectual property rights to a commercially successful product have

been stripped without a hearing. Instead of having to pay a personal injury judgment to an injured plaintiff, Telelex must cede its property rights to its Canadian competitor.

The district court's invalidation of Teleflex's patent without a hearing or oral argument is even more troubling in light of the district court's recognition that Teleflex's patent is presumed valid and that Petitioner "bears the burden of proving facts that establish invalidity by clear and convincing evidence." *Teleflex, Inc. v. KSR Int'l Co.*, 298 F. Supp. 2d 581, 587 (E.D. Mich. 2003).

One of the prerequisites for patentability is that the claimed invention is nonobvious within the framework of 35 U.S.C. section 103(a). The Court established a test for "nonobviousness" under section 103(a) in *Graham v. John Deere Co.* 383 U.S. 1 (1966).

The test involves "several basic factual inquiries" that establish (or refute) nonobviousness. This Court recognized forty years ago that there may "be difficulties in applying the nonobviousness test" but also recognized that the test would refine and mature over the years through "case-by-case development." *Id.* at 18.

The Court of Appeals for the Federal Circuit has refined the *Graham* test over the years through "case-by-case development." To avoid statutorily-proscribed "hindsight bias" the Federal Circuit has held that a party challenging a patent under section 103(a) cannot simply cobble together prior art from previous years or decades and claim that the patented invention was an obvious extension of prior art. The Federal Circuit requires the party challenging the patent to demonstrate a motivation to combine the various prior art into the new invention.

The Federal Circuit's "motivation-to-combine" test balances the concern that obvious extensions of prior art are not subject to a patent monopoly against the concern of patent holders that their intellectual property rights will not be invalidated by a cobbling together of prior art references. This careful balancing of interests is particularly important in today's "flat world" economy where intellectual property is precious and easily pirated.

Like many judicial tests, the Federal Circuit's "motivation-to-combine" test demands some intellectual rigor in its application. However, the "motivation-to-combine" test is not inflexible and it definitely does not mandate, as some have claimed, that the "motivation-to-combine" be found, expressly, in the prior art references.

The Federal Circuit's requirement that a party articulate--in the prior art, in the general industry knowledge or through evidence of the knowledge of a person having ordinary skill in the art--the "motivation-to-combine" is a reasonable protection for patent holders. This is particularly so because patents are presumed valid and because "obviousness" must be proven by clear and convincing evidence.

This case illustrates why this Court should require some level of intellectual rigor on the part of a party challenging a patent under section 103(a).

This Court should extend at least as much protection to a patent holder as it does to a product liability defendant. The concerns articulated by the United States and the *amici* are, at bottom, procedural concerns. Those concerns are best addressed by the existing procedures this Court has in place. A helpful analogy to the judicial determination of obviousness is the judicial determination of expert witness

reliability found in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 590 U.S. 579 (1993).

If this Court extends the procedural protections found in *Daubert* and its prodigy to the obviousness test under *Graham v. John Deere Co.*, then the Court will have struck a fair balance between the concerns about lax patentability standards and the concerns of valid patent holders.

Argument

A. The District Court Did Not Provide Adequate Procedural Protection to the Patent Holder, Teleflex.

Teleflex's patent is presumed valid. 35 U.S.C. § 282. A party challenging Teleflex's patent must establish invalidity by clear and convincing evidence. *See Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1 (1934); *Moba, B. V. v. Diamond Automation, Inc.*, 325 F3d 1306, 1319 (Fed. Cir. 2003).

The ultimate question of patent validity is a question of law. *Graham*, 383 U.S. at 17. Of the three prerequisites for patentability,[2] however, nonobviousness lends itself to a predicate factual inquiry before the Court determines nonobviousness as a matter of law. *Id.*

This Court identified the elements of the predicate factual inquiry to be undertaken by a district court:

1. the scope and content of the prior art are to be determined;
2. differences between the prior art and the claims at issue are to be ascertained; and

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[2] Novelty, 35 U.S.C. section 101; utility, 35 U.S.C. section 102, and nonobviousness, 35 U.S.C. section 103.

3. the level of ordinary skill in the pertinent art must be resolved.

Id.

The Court also identified a non-exhaustive list of "secondary considerations" that are relevant indicia of obviousness or nonobviousness:

(a) commercial success,
(b) long felt but unsolved needs,
(c) failure of others, etc.

Id. at 18-19.

This Court expressly recognized that its predicate factual inquiries "focus attention on economic and motivational rather than technical issues" but held that these economic and motivational inquiries were a necessary safeguard for patent holders: "They may also serve to guard against *slipping into use of hindsight* and to resist the *temptation to read into the prior art the teachings of the invention in issue*." Id. at 36 (emphasis added) (internal citations omitted).

Finally, this Court cautioned that "*strict observance* of the requirements laid down here will result in that uniformity and definiteness which Congress called for." *Id.* at 18. (emphasis added).

In contrast to the "strict observance of the requirements laid down" in *Graham*, the district court here invalidated Teleflex's patent under section 103(a) without a hearing and without oral argument. *See Teleflex*, 298 F. Supp. 2d at 583, 591, 596.

The district court invalidated Teleflex's patent based on a three-link chain of reasoning:

(a) the Patent Examiner originally rejected Teleflex's patent application based on a

finding of obviousness in the combination of the Redding (U. S. Patent No. 5,460,061) and Smith (U. S. Patent No. 5,063,811) patents;

Id. at 594-95;

(b) the Asano patent (U. S. Patent No. 5,010,782) was never cited to the Examiner as prior art; and

Id. at 589;

(c) "If the Asano patent had been cited to the Examiner, he would have found the combination of Asano and Smith to be obvious just as he found the combination of Redding and Smith to be obvious."

Id. at 595.

What is troubling is that the sole evidentiary basis for the first and third links in this chain is one conclusory affidavit from Petitioner's expert – a patent lawyer named Grauer. *See* Report of Defendant's Expert Witness Richard D. Grauer ("Grauer Report"), 2003 WL 24219933. In fact, the district court's opinion is a near verbatim recitation of Attorney Grauer's affidavit: *Compare Teleflex*, 298 F. Supp. at 595: "If the Asano patent had been cited to the Examiner, he would have found the combination of Asano and Smith to be obvious just as he found the combination of Redding and Smith to be obvious," *with* 2003 WL 24219933, § E: "It would have been obvious to combine the previously applied electronic throttle control of Smith with the adjustable-position pedal system of Asano."

Even more troubling, Grauer supports his opinion (and by extension, the district court's ruling) based on *his personal translation* of the admittedly "garbled" office action rejecting the application based obviousness: "the

Examiner's first sentence was somewhat garbled. Based upon my experience as an examiner and practitioner, it is my opinion that the Examiner's intended meaning was . . . " *See id.* at n.3.

Naturally, as the district court held neither a hearing nor oral argument, Teleflex could not test the bases for Petitioner's expert's opinion in the crucible of cross examination; the district court had no opportunity to assess the credibility or demeanor of the expert and the appellate courts have been denied the opportunity to review a thorough record.

Instead, Teleflex was stripped of its patent based on a paper record and this Court is now asked to resolve a matter of global import based on cross-moving affidavits. This Court can and should demand more of a record. Further, this Court should sustain the Federal Circuit's insistence on a more adequate record by affirming.

B. The Federal Circuit Has Refined the *Graham* Test Through "Case-By-Case Development."

In creating the fact-based *Graham* test, this Court expressly recognized that there may "be difficulties in applying the nonobviousness test." *Graham*, 383 U.S. at 18. This Court foresaw a multitude of varying factual scenarios: "What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context." *Id.* The Court was confident, however, that its fact-based obviousness test "should be amenable to a case-by-case development." *Id.*

The Court of Appeals for Federal Circuit has developed the *Graham* test through "case-by-case development" over the past decades.

To avoid statutorily proscribed "hindsight bias", the Federal Circuit has held that a party challenging a patent under section 103(a) cannot simply cobble together prior art from previous years or decades and claim that the patented invention was an obvious extension of prior art: "Mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006).

To prevent hindsight bias and protect the rights of patent holders, the Federal Circuit requires a party challenging a patent to demonstrate a motivation to combine the various prior art into the new invention. *See in re Fulton*, 391 F.3d 1195, 1199-1200 (Fed. Cir. 2004). The "motivation to combine" can come from many sources including

- knowledge generally available to one of ordinary skill in the art;

In re Jones, 958 F.2d 347, 351 (Fed. Cir. 1992);

- the prior art;

Merck & Co., Inc. v. Biocraft Labs., Inc., 874 F.2d 804, 807 (Fed. Cir. 1989);

- the prior art as filtered through the knowledge of one skilled in the art.

Motorola, Inc. v. Interdigital Tech. Corp., 121 F.3d 1461, 1472 (Fed. Cir. 1997).

The Federal Circuit has long held that "There is no requirement that the prior art contain an express suggestion to combine known elements to achieve the claimed invention." *Id.*

The Federal Circuit does insist, however, that a finding of obviousness under section 103(a) be supported by articulable evidence that is either explicit or implicit. See *id.*. ("The record evidence supports the jury's implicit

finding of a suggestion to combine the various references.); *see also Kahn*, 441 F.3d at 988 ("There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.").

The Federal Circuit's requirement that a party articulate--in prior art; in the general industry knowledge or through evidence of the knowledge of a person having ordinary skill in the art – a "motivation to combine" is a reasonable protection for patent holders that is based as much on due process as it is on section 103. *Id.* This is particularly so because patents are presumed valid and because "obviousness" must be proven by clear and convincing evidence. 35 U.S.C. § 282; *Moba*, 325 F.3d at 1319; *see also Radio Corp.*, 293 U.S. at 7 ("A patent regularly issued...is presumed to be valid until the presumption be overcome by convincing evidence of error.").

In sum, the Federal Circuit heeded this Court's advice to refine the *Graham* test through "case-by-case development". *Graham*, 383 U.S. at 18. The Federal Circuit also heeded this Court's admonition concerning the need for intellectual rigor in applying the test:

> We believe that *strict observance of the requirements laid down here will result in that uniformity and definiteness which Congress called for in the 1952 Act.*

Id. (emphasis added).

Current criticisms of the suggestion test are unfounded. Indeed, the Petitioner's "syngergistic" approach to the obviousness inquiry is wholly subjective and would invite hindsight to rule the day, in violation of both the statute and the Court's jurisprudence. Similarly, the United

States' "extraordinary level of innovation" test is wholly subjective and would permit patent challengers to defeat valid patents by cobbling together old prior art to show that a claimed invention may be novel and useful but not "extraordinarily" so. Both alternate tests seek something other than "nonobviousnesss" as required under section 103(a). That being the case, the Petitioner and the supporting amici should take their case to Congress and not this Court.

This Court is bound to apply section 103(a) as drafted by the United States Congress and it has done so in *Graham*. The *Graham* test works. It has been refined by the Federal Circuit, as this Court has instructed, through "case by case development".[3]

The number of US patents granted has grown steadily since the late 1980s, from approximately 90,000 patents granted in 1990 to approximately 170,000 patents granted in 2003. *Science and Engineering Indicators 2006* at 6-28, Fig. 6-22. In fact, US patents have enjoyed a period of nearly uninterrupted growth since the late 1980s. Most if not all inventions arise from a combination of old elements, and it is more and more common for every element of a claimed invention to be found in the prior art. *Kotzab*, 217 F.3d at 1369-70 (citing *In re Rouffet*, 149 F.3d 1350, 1357 (Fed.Cir.1998)).

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[3] To the extent that the United States Patent and Trademark Office deems the Federal Circuit's precedent too lax, this Court can clarify that the Patent and Trademark's findings of fact constitute "substantial evidence" of obviousness or nonobviousness. *See Dickinson v. Zurko*, 527 U.S. 150, 164 (2000). As noted above, the Federal Circuit does not require that the "motivation-to-combine" be found expressly in prior art. As such, the Patent and Trademark Office's expertise, noted in the file, can provide substantial evidence of obviousness or nonobviousness.

In such cases, the dangers of hindsight are virtually unavoidable, without an additional consideration to inform the obviousness analysis, especially in cases "where the very ease with which the invention can be understood may prompt one 'to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.'" *Dembiczak*, 175 F.3d at 999 (quoting *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)).

This case demonstrates why the Federal Circuit's "motivation-to-combine" test is an important procedural safeguard. Here, the district court invalidated Teleflex's commercially successful patent at the behest of Teleflex's Canadian competitor. It did so without a hearing and without oral argument. The district court invalidated Teleflex's "patent regularly issued" based on one affidavit of a patent lawyer retained by Petitioner. Moreover, Petitioner's patent law expert purported to interpret the admittedly "garbled" initial rejection by the Patent Examiner. *See* Grauer Report, 2003 WL 24219933, at n.3. Finally the district court relied upon Grauer's interpretation of the "garbled" initial rejection when it invalidated Teleflex's patent. *See Teleflex*, 298 F. Supp. at 595.

As a holder of valid patent, Teleflex deserved a more thorough hearing before the district court invalidated its patent. Fortunately, as this Court predicted long ago[4], the field of tort law provides a helpful illustration of what process is due under section 103(a).

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[4] This Court marked other fields of the law as guideposts for the then-nascent obviousness inquiry in *Graham*: "The difficulties [in applying the fact-based *Graham* test] however, are comparable to those encountered daily by courts in such frames of reference as negligence and scienter." *Graham*, 383 U.S. at 18.

C. *Daubert* and Its Progeny Illustrate How District Courts Can Resolve The Predicate Factual Issues Identified in *Graham*.

The question of patent validity is a question of law but patent invalidity based on obviousness requires a predicate factual analysis. *See Graham* 383 U.S. at 17-18. Similarly, admissibility is a question of law for the court but requires a predicate factual analysis before a court can rule on an objection to admissibility. *See* FED. RULE OF EVIDENCE 104(a). The Federal Rule of Evidence Advisory Committee Notes reflect that courts will necessarily make predicate factual findings to determine matters of law:

> Often, however, rulings on evidence call for an evaluation in terms of legally set standard. Thus, when a hearsay statement is offered as a declaration against interest, a decision must be made whether it possesses the required against-interest characteristics. These decisions, too, are made by judges.

Advisory Committee Notes to FED. R. EVID. 104(a) (1972).

This Court has recognized that the relevancy of expert witness testimony is a matter of law that requires predicate factual findings. *Daubert*, 509 U.S. at 592-95.

> Faced with a proffer of expert scientific testimony, then, the trial court must determine, at the outset, pursuant to Rule 104(a) whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. *This entails a preliminary assessment of whether the*

> *reasoning or methodology properly can be applied to the facts in issue.*

Id. at 592 (emphasis added).

In *Daubert*, the Court laid out a thorough but flexible methodology for evaluating expert witness testimony under Federal Rules of Evidence 104(a) and 702. *See id.* at 593-95. The Court recognized that the trial court's factual findings and conclusions could lead to the exclusion of some evidence – the "gatekeeping role.. *Id.* at 597. However, this Court concluded that the "gatekeeping role" strikes a fair balance between novel scientific theory and "the particularized resolution of legal disputes". *Id.*

In subsequent opinions, this Court held that the trial court had latitude in the manner in which it executed its *Daubert* "gatekeeping" role. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 151-52 (1999). The Court requires, however, that the district court properly perform its gatekeeping function when a party raises an objection to expert witness testimony. *See id.* at 159 (Scalia, J. concurring).

Over the years, Courts of Appeal have applied and refined this Court's *Daubert* analysis. The Courts of Appeal strongly encourage district courts to hold *Daubert* hearings with live testimony by the experts subjected to cross-examination by the court and counsel: "The most common method for fulfilling this function [the gatekeeping function] is a *Daubert* hearing, although such a process is not specifically mandated." *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000). A *Daubert* hearing is a separate evidentiary hearing involving the examination of witness and findings of fact by the trial court. *See, e.g., Hynes v. Energy West, Inc.*, 211 F.3d 1193, 1204 (10th Cir. 2000); *United States v. Decoud*, 456 F.3d 996,

1013 (9th Cir. 2006); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005); *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 782 (4th Cir. 1998).

Whether or not a trial court holds a *Daubert* hearing, it must develop a full record to allow the Court of Appeals to determine if it properly applied the relevant law:

> For purposes of appellate review, a natural requirement of this function is the creation of a sufficiently developed record in order to allow a determination of whether the district court properly applied the relevant law.

Goebel, 215 F.3d at 1088; *see also United States v. Lee*, 25 F.3d 997, 999 (11th Cir. 1994) ("We encourage district courts to make specific fact findings concerning their application of Rule 702 and *Daubert* . . . such findings will facilitate this court's appellate review.").

Daubert hearings and detailed findings of fact allow an appellate court to determine whether the district court misapplied *Daubert*. *See McClain*, 401 F.3d at 1238 (holding that the trial court abdicated its gatekeeping rule based on complexity of issues). A district court's failure to articulate its gatekeeping analysis on the record requires a remand for further proceedings:

> A review of this case convinces us of the absolute necessity of district court findings on the record. There is not a single explicit statement on the record to indicate that the district court ever conducted any form of *Daubert* analysis whatsoever . . . .

Goebel, 215 F.3d at 1088.

The district court's *Graham* analysis in this case is as flawed as the *Daubert* analysis in *Goebel*. In both cases, the district court provided little evidence that it applied, with intellectual rigor, the test laid out by this Court. In this case the district court engaged in a perfunctory recitation of the *Graham* test as refined by the Federal Circuit but it took no evidence, heard no witnesses and held no hearing. *Compare Teleflex*, 298 F. Supp. 2d at 583, 591, 596 *with Goebel*, 215 F.3d at 1086.

The fact that patents are presumed valid and can only be invalidated by clear and convincing evidence only underscores the need for a thorough hearing for section 103(a) challenges complete with live expert testimony and specific findings of fact by the trial court. This Court should affirm the Federal Circuit and remand this case for further, more thorough proceedings in the District Court.

Conclusion

Millions of patents have been issued over the years. The body of "prior art" expands geometrically. The potential for "hindsight bias" also increases geometrically.

If this Court weakens its *Graham* test as refined by the Federal Circuit and eliminates or dilutes the "motivation to combine" test, then the intellectual property rights of thousands of patent holders will also be weakened. The Petitioner's "synergistic" test is wholly subjective and effectively deletes § 103(a) from the statute. The United States' "extraordinary level of innovation" is equally subjective. Under either proposed test, a party bent on pirating intellectual property rights need only cobble together enough "prior art" to establish a prima facie case for obviousness. The Federal Circuit "motivation to combine"

test is a barrier to such schemes because it requires a patent challenger to demonstrate that the new invention is not "obvious" in hindsight only. The UIA joins with the Respondents and numerous *amici* in urging the preservation of the *Graham* test as refined by the Federal Circuit. In today's "flat world" economy the intellectual property of American companies like Teleflex is precious and easily pirated. This Court should not now weaken the protections for intellectual property that are already threatened overseas.

The real concerns of the United States and most *amici* are concerns of procedure. They think it is too easy for a patent holder to defeat, at summary judgment, challenges based on obviousness. They think this causes too many jury trials. To the extent those concerns are valid and not simply anecdotal, this Court should require district courts to hold hearings on section 103(a) challenges.

Like *Daubert* hearings, these hearings will weed out weak cases that should not go forward. Also, like *Daubert* hearings, these hearings will produce a thorough record and allow rigorous appellate review. The process has worked well in evidentiary law. It should work well in patent law. Such hearings will protect against lax patentability standards and will protect valid patent holders.

Respectfully Submitted,

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